

## The fc 2 Female Condom

### Why fc 2?

- Statistics – 60% of HIV+ persons are women...receiving only 17% of resources
- 6 – 9 billion MCs distributed annually but only 12 million fc 1
- Primary reason given – cost
- **Objective:** change material to allow large volume production = lower the cost!

## What is ..... fc 2 vs fc 1

- Same *design*
- Same *instructions for use*
- Same *high quality*
- *Different material*
- *New volume-sensitive manufacturing process*



## Studies Show

- Specifications almost identical to **fc 1**
- Safety Studies good results: no issues
- Shelf Life 5 years (*accelerated studies*)
- Clinical Studies (*accepted for publication*)
  - **fc 2** performs statistically the same as **fc 1**
    - Rips, tears, slippage
    - Acceptability
    - No allergies

## Regulatory information

- Received CE mark for product and manufacturing
- Under WHO review
- In discussions with FDA regarding requirements

## fc 2 Availability

- Validated manufacturing process
- Scale-up quick and uncomplicated
- Ready to promptly scale-up once demand is established
- Quantity delivery could begin in December, 2005

## Price/volume Costing

- Price/volume coalition plan:

*FHC is prepared to form a process which will allow developing countries to **aggregate purchase orders** so as to receive the lowest possible price. FHC will call a meeting of procurement groups to help in forming a process that hopefully will work efficiently for all.*

## Price Volume Scale

<b>FC1</b>	0.75 US cents
<b>FC2</b> <60 million	0.60
60 – 120 million	0.38
120 – 200 million	0.31
200 – 300 million	0.22
>300 million	TBD
<i>At 200 million, <b>only 3%</b> of male condom volume</i>	

## Cost Effectiveness Study\*

\*assumes: correct use, 3 different levels of national uptake, 2 different costs for FC2

Top Line results -- rounded

### South Africa

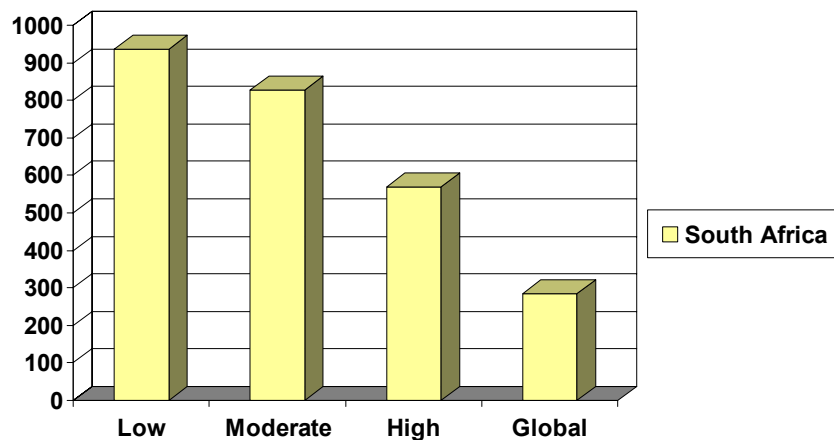
- Distribution range
  - 2.5M to 42M
- HIV averted
  - 1,750 to 31,000
- Cost/infection averted
  - \$290 to \$940
- Medical Costs saved\*
  - \$1M to \$38M

### Brazil

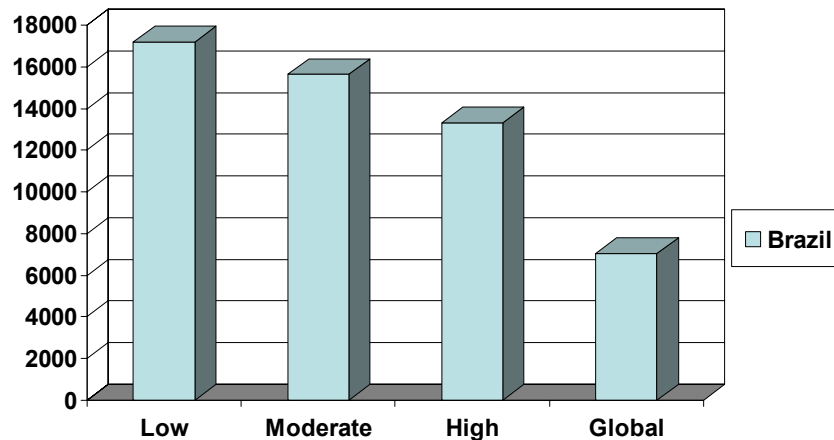
- 3M to 65M
- 87 to 1,970
- \$7000 to \$17,000
- \$0.4M to \$29 M

\*over and above the cost of the FC2 program

## Cost per HIV Infection Prevented by Uptake Level (vs Status Quo)



## Cost per HIV Infection Prevented by Uptake Level (vs Status Quo)



## FHC's next steps

- Determine over-all **demand** for **fc 2**
  - Completion of WHO review
  - General inquiries and purchase orders starting now
  - Define the price/volume coalition process
- Begin large\* **production run** and product distribution by December, 2005
- Finalize **scale-up timing** to meet volume demands in 2006
  - Fully dedicated line/s
  - Transition FC1 to FC2

\* based on demand estimates

## What is next for Product Class?

- *What I believe*
    - In order to change the system we have to do things differently
    - Two critical aspects
      - Not a product, but a **program**
      - **Coalition** of effort
    - Need to **apply current state of art** technologies to education outreach and delivery to GPS
      - Tom Friedman\* – ‘triple convergence’
      - Systems Biology
        - Micro-credit—education out reach--prenatal care--HIV prevention etc
        - ‘Insourcing’ with delivery
- \*US journalist—The World is Flat

## Where is the FC Product-Class growing?

- Where --- the HIV/AIDS epidemic is
  - Where --- women realize their risk and **demand** access
  - When --- donors recognize that women **must have** and **deserve** to have this method .....
- which I say must begin NOW!**